REMARKS

The present application is directed to methods, devices, and kits for the detection and concentration or isolation of an analyte. In particular, the application relates to the concentration of an analyte using an assay such as an immunoassay to facilitate confirmation of a positive assay result.

Claims 8, 11-19, and 21-25 have been withdrawn as being directed to a non-elected invention. Claims 1-7, 9, 10, and 20 are pending. Favorable consideration of the currently pending claims is respectfully requested in light of the following amendments and remarks. No new matter is added and support for the amendments may be found throughout the specification and original claims.

Claim rejections under 35 U.S.C. § 102(b)

In the Office Action of May 31, 2005, the Examiner rejected Claims 9, 10 and 20 under 35 U.S.C. § 102(b) as being anticipated by Noda *et al* (U.S. Patent No. 5,900,379). The Examiner concluded that Noda discloses a test kit comprising a lateral flow device having a section that is removable. According to the Examiner, the removal section comprises a capture region where immobilized antibodies are used to capture an analyte.

Applicants respectfully submit that the amended Claims overcome the Examiner's rejection. Noda *et al* disclose an analytical device comprising, in part, a cassette (see claims 1-2). The cassette is defined as a strip containing a first absorbent material, a membrane immunoassay, and a second absorbent material *attached to* a cassette support means (see column 5, lines 58-61; and column 7, line 66 through column 8, line 1). Noda *et al* teach that a first absorbent material, a second absorbent material, or both may be removed from the cassette (see column 4, lines 9-11; and claim 15). The entire cassette, then, can either be discarded, **or** the first absorbent material and second absorbent material can be removed, leaving the **attached** results section to be stored (see column 5, lines 35-44; and column 11,

example 1). Nothing in the Noda patent discloses a detection zone that is entirely separable from the remainder of the device. The instant claims clearly state that the portion of the device containing the bound analyte and immobilized binding partner (the detection zone) is separated or separable from the remainder of the device. Applicants respectfully submit that Noda *et al* fail to teach or even suggest the removal or isolation of the membrane immunoassay (the detection zone) from the cassette (the device).

Furthermore, Claims 9 and 10 have been amended to clarify that the detection zone is capable of being separated from the remainder of the device as well as the other zones and analyzed for information regarding the bound analyte. Support for this amendment can be found on, at least, page 3, lines 17-18, lines 24-27, and line 35 through page 4, line 2; page 4, lines 15-20; page 5, lines 19-20; and page 15, lines 11-16. Therefore, the claims now state that the portion of the device containing the bound analyte and immobilized binding partner (the detection zone) is separated or separable from other zones and the remainder of the device and analyzed to provide information regarding the suspected analyte. Noda *et al* only disclose means for the *storage* of a results section that is still attached to the device. Nothing in the Noda patent teaches or suggests the *removal and analysis* of the portion of the device containing the bound analyte and immobilized binding partner from all other zones and the remainder of the device as claimed in the present application. Accordingly, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

Claim rejections under 35 U.S.C. § 102(e)

In the Office Action of May 31, 2005, the Examiner rejected Claims 1-4, 7, 9, 10 and 20 under 35 U.S.C. § 102(e) as being anticipated by LaBorde (U.S. Patent No. 6,607,922). The Examiner states that LaBorde discloses an immunochromatographic assay using superparamagnetic beads or particles coupled with antibodies to capture an analyte in a sample. The particles are disposed on a test strip that can be removed from a support member for archival or analysis. The Examiner concludes that even though LaBorde does not

specifically teach a test kit comprising such a device, LaBorde anticipates the claims of the present application.

Applicants respectfully submit that the amended claims overcome the Examiner's rejection. LaBorde teaches an immunochromatographic assay **method** that relates broadly to lateral flow devices employing superparamagnetic particles as labels for the analyte to be detected. The bound complexes are captured in a predetermined area of the porous analytical membrane termed the "capture region" or "capture zone" (see column 3, line 1; and element 14 of the drawings). The lateral flow **device** of LaBorde contains: an assay support member (element 11 of drawings); a sample receiving element (element 17 of drawings); an immunoassay test strip containing a porous analytical membrane (element 13 of the drawings); at least one **capture region** (element 14 of the drawings); a backing member (element 12 of drawings); and a protective member (element 15 of drawings) with at least one magnetic standard line printed on the protective membrane (element 16 of the drawings). The Examiner states that LaBorde anticipates the instant claims because the pending claims recite removal of the portion containing bound analyte from *the remainder of the device*. The Examiner concluded that removing the test strip from the remainder of the device leaves open the interpretation that the "remainder" is the backing support strip. Since the pending claims are not limited to only the removal of the detection zone and nothing else, the Examiner concluded that the removal of the entire test strip disclosed in the LaBorde patent anticipates the instant claims.

Applicants respectfully submit that the amended claims overcome the Examiner's rejection. Particularly, Claims 1, 7, 9, and 10 have been amended to clarify that the detection zone is separated or separable from the other zones as well as the remainder of the device. Support for this amendment can be found on, at least, page 3, lines 17-18, lines 24-27, and line 35 through page 4, line 2; page 4, lines 15-20; page 5, lines 19-20; and page 15, lines 11-16. Nothing in the LaBorde patent teaches or suggests separating the detection zone containing the bound analyte and the immobilized binding partner from the other zones and

the remainder of the device. Indeed, LaBorde suggests the removal and analysis of the entire test strip and not a portion thereof (See column 5, lines 47-59 and Figure 5).

Applicants respectfully submit that neither the method claims as provided herein, nor the device and kit as claimed herein are taught or suggested by LaBorde. Accordingly, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(e).

Claim rejections under 35 U.S.C. § 103(a)

In the Office Action of May 31, 2005, the Examiner rejected Claims 1, 3-6, 9, and 10 under 35 U.S.C. §103(a) as being unpatenable over Benjamin *et al* (U.S. Patent No. 5,491,068) in light of Whitehead *et al* (U.S. Patent No. 4,695,393). The Examiner states that Benjamin discloses a method comprising contacting a sample with magnetic solid support beads having antibodies immobilized thereon. If present, the target selected bacteria cells bind to the antibodies, and the beads with attached immobilized bacteria are then washed to remove any remaining sample. The Examiner concluded that the Benjamin patent differs from the instant invention only in that it fails to teach the magnetic support beads are part of a device. The Examiner further states that the Whitehead patent teaches magnetic beads that are deemed suitable by the Benjamin patent. Whitehead teaches that magnetic tubes are placed in polypropylene tubes, and after samples and labels have been added, the tubes are placed on a magnetic rack consisting of a test tube holder with a cylindrical button magnet at the bottom of each tube. The magnetic particles with antibody and bound tracer are pulled to the bottom of the tube, allowing the unbound tracer to be removed. The Examiner concluded that the tubes containing the magnetic particles taught by Whitehead is the equivalent of the device claimed in the instant application. Because the magnetic beads of Benjamin must necessarily be in a container or tube in order to function, the Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device taught by Whitehead in the method disclosed by Benjamin.

Applicants respectfully submit that the amended claims overcome the Examiner's rejection. Benjamin is directed to a method for detecting the presence of organisms capable of being cultured. Whitehead, on the other hand, is directed to a process for the preparation of magnetic particles to which a wide variety of molecules may be coupled. The Whitehead process uses a magnet to collect particles separated from the unbound tracer. Together, Benjamin and Whitehead both teach the collection of bound particles using magnetic means. The instant invention discloses that the Benjamin/Whitehead approach is both expensive and time consuming (see page 2, line 34 through page 3, line 6). Therefore, one of ordinary skill in the art looking to provide a rapid method for confirming the results of an assay would not look to Benjamin and Whitehead for the answer.

The Examiner concludes that the Whitehead test tubes containing the magnetic particles are equivalent to the device of the present invention. Applicants respectfully disagree with the Examiner's conclusion. The Whitehead test tubes require the insertion of tracer and magnetic particles, among other things (see column 21, lines 40-54). In Whitehead, the magnetic particles and bound tracer are magnetically pulled to the bottom of the tube. Nothing in Whitehead teaches or suggests the use of a lateral flow device to collect suspected analytes. The amended Claims state that the instant device comprises a plurality of zones, at least one of which is a detection zone that is separable from the other zones and the remainder of the device. The instant device exists before the placing of a sample on the device (see Claim 1). Whitehead, however, requires the insertion of magnetic particles along with the tracer sample. Further, when the magnetic particles and bound tracer are removed from the Whitehead test tube, a device ("the test tubes containing the magnetic particles") no longer exists. However, in the instant invention, when the detection zone is separated from the plurality of zones and the remainder of the device, the device of the present invention still exists. In short, the existence of the instant device is not dependent upon the presence of a binding partner as it is in Whitehead. One of ordinary skill in the art would not be motivated to combine the Whitehead test tube and the Benjamin magnetic bead method to address the

problem solved by the instant invention. Therefore, the instant invention would not have been obvious to one of ordinary skill in the art at the time the invention was made. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

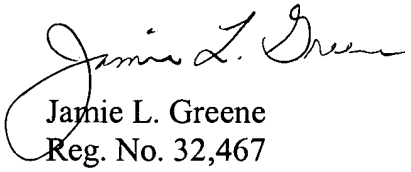
CONCLUSION

Based upon the amendments and remarks provided above, Applicants believe that Claims 1-7, 9, 10 and 20 are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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